Attorney Docket No. TMT-10902/04

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF APPEALS AND INTERFERENCES

Applicant: Michael T. Trese et al.

Serial No.: 10/068,314 Group Art Unit: 3763

Filed: February 6, 2002 Examiner: Matthew F. DeSanto

For: METHOD FOR VITREOUS LIQUEFACTION

REPLY BRIEF

Mail Stop Reply Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant wishes to reply to a few points raised by the Examiner in his answer:

A. The Examiner is correct in noting that substantively there are two separate and distinct outstanding rejections and that the rejection highlighted in the Appeal Brief Section VI.C is subsumed within the rejection articulated in Appeal Brief Section VI.B. Appellant does not believe that any misstatements made in the main brief to this effect have any effect on the arguments on patentability contained therein.

B. Appellant submits that that the first full paragraph of page 6 of the Examiner's Answer highlights a basis for reversal of the outstanding rejections. This paragraph is reproduced below as a courtesy and the value it provides in focusing the issues before the Board.

> The applicant argues that the dose of 0.4 in both prior art references fails to teach liquefaction, which the examiner disagrees with. Both prior art references teach plasmin injected in the eye and then incubated, which is the exact same method claimed by the applicant. The only difference is the dose size. The fact that both references teach a plasmin injected into the eye and then incubated

> would cause some form of liquefaction. The examiner agrees that prior art reference[s] never disclose complete liquefaction of the vitreous of the eye, but both references disclose some type of liquefaction.

Appellant submits that the Office position that the prior art references teach the same method as that found in the claims before the Board, save for the dose of plasmin is inconsistent with the above admission that the prior art "never disclose complete liquefaction of the vitreous of the eye, but both references disclose some type of liquefaction." Thus, one can infer that an additional difference exists between the prior art and the claims that are the subject of this appeal: the ability to achieve complete liquefaction.

Appellant submits that to support the rejections on Appeal, the clear claim language as to the creation of a liquefied vitreous has been interpreted as "creation of any amount of viscosity reduction in vitreous." Appellant submits that the interpretation so applied is improper and grounds for reversal.

Additionally, the record does not disclose the nature of the incomplete liquefaction of finding in the prior art references. However, even if this incomplete liquefaction were an articulated position in the record, an inadequate prior art liquefaction should not preclude patentability of complete liquefaction that is the subject of claims on appeal since the need for complete liquefaction is the basis to avoid mechanical instrumentation to detach the vitreous and the ability to aspirate the vitreous with smaller gauge instrumentation. (Detailed in Application, page 1, line 16 – page 2, line 3).

Trese et al. (Ophthalmology) is absolutely silent regarding using plasmin to liquefy the vitreous and restricts its teaching to posterior vitreous detachment in the treatment of macular holes. Trese et al. (Ophthalmology) nowhere uses the word "liquefaction." A finding of even "some type of liquefaction" is submitted to be a speculative exercise in assigning a mechanism to

the treatment of pediatric traumatic macular holes that is not supported by the prior art reference and contrary to the knowledge that plasmin facilitates surgical cleavage of the vitreoretinal interface. (Page 1618, col. 2, last paragraph).

Trese et al. (American) likewise fails to teach reliable liquefaction of human vitreous and thereby making the use vitreous cutter is still necessary to safely remove the partially liquefied vitreous. (Page 1610, 1st column, first full paragraph).

C. The Examiner notes in his answer that the holding of KSR supports affirmation of the outstanding rejections. Appellant notes that the holding of KSR also requires a resolution of ordinary skill in the art and such a resolution has not occurred. With resolution of ordinary skill in the art occurring, Appellant submits that Declarations of record and especially that of Patrick J. Gaffney providing an explanation for the lack of liquefaction in Trese et al. (American) at seemingly similar dosings would carry still further weight.

D. The Declarations of record have been discounted due to the terminology of "streptokinase-plasminogen" versus "plasmin." In the Examiner's Answer, "streptokinase-plasmin" is referenced as a confusing synonym. Appellant notes that there is no such substance. Rather plasminogen is an enzymatically inactive form of plasmin, that forms a lower enzymatic activity complex with the enzymatic activator streptokinase (streptokinase-plasminogen) that is stable at certain ratios (e.g. 1:1) and that only at lower ratios of streptokinase relative to plasminogen is one likely to obtain high enzymatic activity plasmin. (See Gaffney Declaration

Sections 6-8). Appellant submits that the lack of proper consideration afford the Declarations of record based on this misreading is also a basis for reversal.

Respectfully submitted,

Dated: March 7, 2008

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